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| 09/691,344 | 10/18/2000 | Gregory Donoho | LEX-0071-USA | 3961 |

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EXAMINER

MITRA, RITA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/01/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/691,344

Applicant(s)

DONOHO ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3&4. 6) ☐ Other:

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to an isolated nucleic acid molecule comprising at least 24 contiguous bases related to NHP sequences set forth in SEQ ID NO: 3, isolated nucleic acid molecule that encodes the amino acid sequence set forth in SEQ ID NO: 4, wherein the nucleic acid is a cDNA, classified in class 536, subclass 23.1, 23.5
- II. Claim 4, drawn to an isolated nucleic acid molecule encoding the amino acid sequence set forth in SEQ ID NO: 2, classified in class 536, subclass 23.1, 23.5
- III. Claim 5, drawn to an isolated nucleic acid molecule encoding the amino acid sequences set forth in SEQ ID NO: 6, classified in class 536, subclass 23.1, 23.5

The inventions are distinct, each from the other because of the following reasons:

The DNA of groups I, II and III are unrelated. They differ with respect to their structures and physicochemical properties. The polynucleotides have separate and distinct sequences and encode unrelated proteins. Therefore, the inventions are distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a

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diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Attorney Sam Eferian on July 5, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-3. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 5 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 1-3 are currently pending and are under examination.

Oath or declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of inventor Glen Friedrich. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Objection to the Specification

The disclosure is objected to for the following informalities:

The abstract of the disclosure is objected to because the abstract is not descriptive.

Appropriate correction is required. See MPEP § 608.01(b).

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119 (e) is acknowledged. This application claims the benefit of a priority of US Provisional Application No. 60/160285, filed on October 19, 1999 and 60/183583, filed on February 18, 2000. However, the provisional Application 60/160285 fails to provide the sequences set forth in SEQ ID NO: 3 and SEQ ID NO: 4 in support of the priority date claimed. Therefore, the priority date granted is February 18, 2000, which is the filing date of 60/183583.

Information Disclosure Statement

The information disclosure statement filed January 24, 2001 (paper #3) and the supplemental IDS filed February 20, 2001 (paper #4) are acknowledged. The statement in paper #4 indicates that a prior art listed in 1449 (Ref BN) is submitted, however only one page is found, not the entire document. Therefore, PTO-1449 in paper #4 and paper #3 have been placed in the application file and considered with regard the references, which have been submitted. Note that references, which have not been supplied with this application, have been lined through. Consideration of the lined through reference will be made upon compliance with 37CFR 1.98.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 1 encompasses the subject matter that is not defined in the specification. The claim is directed to an isolated nucleic acid molecule comprising at least 24 contiguous bases of nucleotide sequence first disclosed in the NHP gene described in SEQ ID NO: 3. It is clear from the specification that Applicants were in possession of SEQ ID NO: 3 at the time the invention was made. However, the specification, have given no concise definition of the novel human protein (NHP). The specification, only discloses cursory conclusions (see page 2-8), without data to support the findings, which state that the novel human proteins (NHP), share structural similarity with animal CUB domain protein, coagulation factors V and XIII, milk fat globule-EGF factor 8, transcriptional repressor AE-binding protein-1, and neutropilins 1 and 2 (which like the presently described protein, contain both CUB and discoidin domains). The specification further indicates at page 4 that the present invention includes the human DNA sequences presented in the sequence listing, and additionally contemplates any nucleotide sequence encoding a contiguous NHP open reading frame (ORF), or a contiguous exon splice junction that hybridizes to a complement of a DNA sequence presented in the sequence listing under highly stringent conditions. However specification fails to provide any description of the fragments or the contiguous bases within the polynucleotide that retain the activity of the full length NHP which has an activity of the CUB domain protein, or coagulation factors V and XIII, or milk fat globule-EGF factor 8, or transcriptional repressor AE-binding protein-1, or neutropilins 1 protein. Therefore, it requires a written description to make the claimed invention, especially where in claim 1, 24 or more contiguous bases of nucleotide sequence of SEQ ID NO: 3 that would have been included by the claim and for which the specification does not describe with particularity as to the function of NHP protein having CUB domain protein, or coagulation factors V and XIII, or milk fat globule-EGF factor 8, or transcriptional repressor AE-binding protein-1, or neutropilins 1 and 2 protein activity.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claim 1, the specification does not enable the skilled artisan

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to use the claimed polynucleotide because the specification fails to provide a written description of a polynucleotide that has at least 24 contiguous bases of the corresponding polynucleotide sequence that is disclosed in NHP gene.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because of the use of the term “NHP.” An acronym/abbreviation should be preceded by the full spelled out word. Claim 3 is included in the rejection because it is dependent on rejected claim and do not correct the deficiency of the claim from which it depends.

Claim 3 is indefinite because it is not further limiting. It reiterates cDNA, which is inherent in claim 1.

Claim 2 is indefinite because of the use of the word “stringent.” It is not clear whether it is high, moderate or low stringent condition. Recitation of the stringent hybridization condition in the claim will overcome this rejection. Also if the nucleic acid of claim 2 encodes the protein of SEQ ID NO: 4 it must hybridize to complement of the sequence of SEQ ID NO: 3, not to the coding strand of the sequence.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as anticipated by Strachan et al. (US 6,242,419, filed August 26, 1999, issued June 5, 2001). Strachan et al. teach an isolated polynucleotide encoding polypeptide expressed in mammalian fcn-/- lymph node stromal cells. Wherein the polynucleotides were isolated from a cDNA library prepared from lymph node stromal cells (see abstract, col 8, lines 47-50, Example 1 in col 13). Strachan et al. teach a cDNA comprising 31 contiguous bases (position 236-266) of nucleotide sequence of SEQ ID NO: 3 (see alignment result Database: N_Geneseq_032802, Accession NO: AAA96736). Strachan's nucleic acid sequence is considered for a fragment of the nucleic acid sequence set forth in SEQ ID NO: 3 having at least 24 contiguous bases thus anticipating claim 1 of instant application. Strachan's nucleic acid is a cDNA, which was isolated from a cDNA library (claim 3).

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211.

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The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "Karen Cochrane Carlson" followed by a stylized monogram or initials.

KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER

Rita Mitra, Ph.D.

September 22, 2002